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EXAMINER
BRUENJES, CHRISTOPHER P

ART UNIT	PAPER NUMBER
1772	

DATE MAILED: 06/18/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/926,817	Applicant(s) FUJIEDA ET AL
	Examiner Christopher P Bruenjes	Art Unit 1772

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 April 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *18-62* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *18-62* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *18 April 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Drawings

1. The corrected or substitute drawings were received on April 18, 2003. These drawings are acceptable.

WITHDRAWN REJECTIONS

2. The objections to the drawings, abstract and specification of record in Paper #5, Pages 2-3 Paragraphs 1-3 have been withdrawn due to Applicant's amendment in Paper #8 and 10.

3. The 35 U.S.C. 112 rejections of claims 1-17 of record in Paper #5, Pages 3-5 Paragraph 4 have been withdrawn due to Applicant's amendment in Paper #10.

4. The 35 U.S.C. 102 rejections of claims 1-4, 13-15, and 17 of record in Paper #5, Pages 6-7 Paragraph 5 have been withdrawn due to Applicant's amendment in Paper #10.

5. The 35 U.S.C. 103 rejections of claims 5-9 of record in paper #5, Pages 8-9 Paragraph 6 have been withdrawn due to Applicant's amendment in Paper #10.

6. The 35 U.S.C. 103 rejections of claims 10-12 of record in Paper #5, Pages 9—11 Paragraph 7 have been withdrawn due to Applicant's amendment in Paper #10.

7. The 35 U.S.C. 103 rejection of claim 16 of record in Paper #5, Pages 11-12 Paragraph 8 has been withdrawn due to Applicant's amendment in Paper #10.

NEW REJECTIONS

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claim 43 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The limitation that the inner and outer layer

is formed of a resin containing 70 to 100% polypropylene resin is new matter because the specification explicitly states on Page 9 that the mass percentage polypropylene resin in the connection layer, which is the outer and/or inner layer, is between 45 and 70%. Further, only the inner layer is disclosed as having a composition with 70 to 100% polypropylene resin.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claims 18-62 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claims 18 and 41, the limitations that the tube has a shear peel strength of less than 35 N or 180° peel strength of less than 10N, render the claim vague and indefinite because it is not understood for what substrate the tube has these peel strength values.

Claims 39 and 61 recite the limitation "the medical device of claim 18" in line 1. There is insufficient antecedent basis for this limitation in the claim.

Claims 19-38, 40, 42-60, and 62 are rejected as dependent on rejected claims.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. Claims 18-20, 22-36, 41-43, and 45-58 are rejected under 35 U.S.C. 102(b) as being anticipated by Kodama et al (JP 09-254339).

Kodama et al anticipate a tube consisting of two layer or three layer laminated body for forming a tube or medical product (see abstract and p.9 Paragraph 26 of machine translation). The tube consists of a base material or intermediate layer in the three-layer body having 95-20% polypropylene resin and 5-80% hydrogenated diene-based polymer. The inner and/or outer layer of the body consists of 100-50% polypropylene resin and 0-50% hydrogenated diene-based polymer (see abstract). The hydrogenated diene-based polymer in either the base layer or the other layer comprises a random copolymer or block copolymer

comprising styrene and butadiene, isoprene, or a mixture of isoprene and butadiene (p.3 Paragraphs 6-7 of machine translation). The styrene content is between 5 and 60% and the vinyl content of the butadiene and/or isoprene is 50% or more. The rate of hydrogenation of the hydrogenated diene system is 90% or more (p.3, Paragraph 9 of machine translation). The elastic modulus of the entire tube is less than 30MPa (p.6, Paragraph 13 of machine translation), which is the same as the entire tube of the instant invention, therefore the flexural modulus of the polypropylene resin in the two resin is inherently the same in Komada et al as the instant invention. Because the Komada et al body is formed form the same composition, structure, and method the body inherently has peel strength similar to the peel strength of the instant invention. Further, note the substrate that the tube defined in claim 18 and 41 is not described and the tube of Komada et al would have shear peel strength below 30N and 180° peel strength below 10N depending on the substrate the tube is in contact with. The body is an article used in the medical field.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

11. Claims 21 and 44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kodama et al (JP 09-254339).

Kodama et al teach all that is claimed in claims 18 and 41 and teach that the ratio of thickness of the base material layer and the other layer is suitably chosen according to the property and use of the product (p.5 paragraph 12 of machine translation), but fails to explicitly teach the claimed thickness ratio. It would have been obvious to one having ordinary skill in the art at the time the applicant's invention was made to select the ratio of thickness of the layers within the claimed range, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art, absent the showing of unexpected result. *In re Boesch*, 205 USPQ 215 (CCPA 1980).

12. Claims 37-40 and 59-62 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kodama et al (JP 09-254339).

Kodama et al teach all that is claimed in claims 18 and 41 and teach that the article is a medical-application packaging film, abandonment bag or hygienic goods, but fails to explicitly teach that the tube is sterilized, or that the tube is connected to a medical device, or that the tube is a blood tube, infusion tube, catheter, balloon catheter, or part of a circuit for extracorporeal circulation. However, it would have been obvious to one of ordinary skill in the art at the time the applicant's invention was made to shape the body used in medical applications of Kodama et al to form bodies that are used in forming the particular articles listed above. Furthermore, the intended use of an article receives little patentable weight because articles are defined by their structure not merely stating a use for the article. One of ordinary skill in the art would have also recognized that medical-application films, bags, and goods are sterilized, in order to protect the user from diseases transmitted by the articles.

Therefore, it would have been obvious to one having ordinary skill in the art at the time the applicant's invention was made to sterilize the medical-application films, bags and goods taught by Kodama et al, in order to protect the people using the articles from diseases and injections transmitted by unsterilized medical articles.

13. Claims 18-31, 35, 37-45 and 49-62 are rejected under 35 U.S.C. 103(a) as being unpatentable over Heilmann et al (USPN 5,928,744) in view of Strassmann (USPN 6,127,009).

Heilmann et al teach a multi-layered tube composed of at least two layers (Fig.1) wherein at least one layer or base layer of said layers is a layer made of a resin composition comprising 0-50 mass% of a polypropylene resin and 100-50% of a copolymer of hydrogenated styrene-butadiene-styrene, hydrogenated styrene-isoprene-styrene, such as SEBS or SEPS (col.6, l.8-16) or a combination of SEBS and SEPS (col.8, l.65-67). At least one other layer or connection layer is attached to the first layer having a composition comprising 50-100% polyethylene and 0-50% of a copolymer of hydrogenated diene system as listed above for the other layer. An optional third layer or cover layer is a layer formed of a resin composition comprising 40-60

mass% of a polypropylene resin and 60-40 mass% of the above copolymer (col.6, l.1-5 and col.8, l.62-67). The first or base layer and second or connection layers combine with the first layer forming the outermost or innermost layer (col.5, l.9-10). When forming a tube with 3 or more layers the first layer is an intermediate layer and the second layer is an inside and/or outside layer and the third layer is formed on the opposite side of the first layer from the second layer (col.5, l.45-46). The first layer has a thickness of between 900-980 micrometers, and the second layer has a thickness of between 10-50 micrometers (col.6, l.1-28). In the multi-layered tube styrene is the vinyl aromatic compound. The tube is a multi-layered tube for medical use, in particular as a fluid line in dialysis, infusion, or artificial feeding, primarily in connection with connectors or medical bags (abstract). Heilmann et al teach the tubes are in connection with medical bags; therefore inherently a medical device comprising the multi-layered tube recited above and a medical bag are connected. Heilmann et al fail to explicitly teach that the second layer is formed from polypropylene rather than polyethylene. However, Strassmann teaches a multi-layered tube joined to a flexible polymer bag used in medical

devices (Fig.1) in which polypropylene is used in making the tube rather than polyethylene because polyethylene had to be roughened to prevent the inside faces from sticking together when the inner layer of the bag was polyethylene (col.4, l.32-35). If the second layer were used as the outer layer the polyethylene would also stick to other tubes when sanitized together. Substituting polypropylene for polyethylene when forming a flexible multi-layered tube for medical devices the processing steps of roughening are avoided, and furthermore the tube has even better transparency (col.4, l.37-39). It is also notoriously well known in the art that polypropylene resins and polyethylene resins bond to themselves much better than to other resins, therefore substituting polypropylene for polyethylene in the second layer will improve the bond between the first and second layers. One of ordinary skill in the art would have recognized that polypropylene is substituted for polyethylene when forming flexible multi-layered tubes in order to avoid the processing steps of roughening and improve transparency of the tube and the bond formed between the layers, as taught by Strassmann.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the applicant's

invention was made to substitute polypropylene for polyethylene in the second layer of Heilmann et al, in order to decrease process steps, improve the transparency of the tube and to increase the bond strength between the layers of the multi-layered tube as taught by Strassmann.

Additionally with regards to claims 18 and 41, neither Heilmann et al nor Strassmann explicitly teach that the outermost layer of the tube has a shear peel strength of less than 35N or 180° peel strength of less than 10N after autoclave sterilization at 121°C for 20 minutes. However, there is no mention of what substrate the outermost layer is in contact with having these peel strength parameters and it is well known that the tube of Heilmann et al or Strassmann would have peel strength less than 10N when against non-compatible substrates. Also with regards to claims 41-62, the embodiment of Heilmann et al in which the third layer or cover layer is used as the outermost layer, the composition of that layer is the same as the outermost layer of the instant invention and therefore the peel strength values would also be the same. Further with regards to claims 36 and 58, Heilmann et al uses all of the same block copolymers to combine with the polypropylene resin as the applicant does to form the layers of the

medical tube, and the tube is used for the same purposes. Routine experimentation in Heilmann et al would obviously produce similar values for the flexural modulus of the polypropylene resin because without similar values the tube using the same components as applicant would be either dramatically stiff or overly flexible when used as a medical tubing for a fluid line in dialysis, infusion, or artificial feeding.

14. Claims 32-34 and 46-48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Heilmann et al in view of Strassmann as applied to claims 18 and 41 and in further view of Takeuchi et al (USPN 5,264,488).

Heilmann et al and Strassmann combined teach all that is claimed in claim 18 and 41 and teach a hydrogenated block copolymer of SEBS, SEPS, or a combination of the two, which would inherently have a component weight ratio between 5/95 and 95/5 (col.8, l.65-67). Heilmann et al fail to explicitly teach the percentage of styrene, the vinyl bond content of the isoprene and butadiene, and the percentage of hydrogenation. However, Takeuchi et al teach a medical device comprising a layer comprising 10-50wt% of a polyolefin resin and 1-89wt% of a hydrogenated block

copolymer composed of a polymer block having a vinyl aromatic compound preferably styrene and a polymer block having a conjugate diene compound, which includes hydrogenated SBS and SIS. Takeuchi et al also teach specific characteristics of the hydrogenated block copolymer including that at least 90% of the block copolymer is hydrogenated because if the hydrogenation is less the block copolymer becomes deficient in heat resistance and weatherability (col.3, l.41-49), which is needed in order to preserve the tube when subjected to sterilization. The vinyl bond content of the diene compound is in the range of 25-95mol% because if the content is less than 25mol% or more than 95mol% then the block shows a crystalline structure and assumes a resinous quality owing respectively to its separate components such as hydrogenated butadiene separates into ethylene and butylene, which would cause the block copolymer to lose its functionality (col.3, l.16-25). The amount of the vinyl aromatic compound to be used in the block copolymer is not more than 35wt% because if this amount exceeds 35wt%, then the glass transition point of the block copolymer is unduly high and the dynamic properties of the component are unduly low (col.3, l.8-15).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the applicant's invention was made to make the hydrogenated block copolymers of Heilmann et al have the specifications of the hydrogenated block copolymers in Takeuchi et al in order to keep the glass transition point low, the hydrogenated diene compound from crystallizing and losing its functionality and make the tube efficient in weatherability and heat resistance to withstand sterilization, as taught by Takeuchi et al.

ANSWERS TO APPLICANT'S ARGUMENTS

15. Applicant's arguments filed in Paper #10 regarding the objections to the drawings, abstract, specification, and the 35 U.S.C. 112 rejections of record have been considered but are moot since the rejections have been withdrawn.

16. Applicant's arguments filed in Paper #10 regarding the 35 U.S.C. 102 rejections of claims 1-4, 13-15 and 17 as anticipated by Heilmann et al have been considered but are moot since the rejections have been withdrawn. However, the arguments with regard to the newly added claims have been fully considered but they are not persuasive.

In response to applicant's argument that Heilmann tubes are different from the present invention because the Heilmann tubes have a dimensionally unstable connection layer, these features upon which the applicant relies are not recited in the rejected claims. The limitation regarding the peel strength of the outermost layer does not read over Heilmann because one embodiment of Heilmann has the cover layer not the connection layer as the outermost layer, and because the connection layer of Heilmann would have a peel strength meeting the limitations when in contact with a non-compatible substrate, and no specific substrate is claimed.

17. Applicant's arguments filed in Paper #10 regarding the 35 U.S.C. 103 rejections of claims 5-9 over Heilmann et al in view of Strassmann of record have been considered but are moot since the rejections have been withdrawn.

18. Applicant's arguments filed in Paper #10 regarding the 35 U.S.C. 103 rejections of claims 10-12 over Heilmann et al in view of Takeuchi et al of record have been considered but are moot since the rejections have been withdrawn.

19. Applicant's arguments filed in Paper #10 regarding the 35 U.S.C. 103 rejection of claims 16 over Heilmann et al of record have been considered but are moot since the rejection has been withdrawn.

Conclusion

20. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Ishikawa et al (USPN 5,529,821); Mueller (USPN 6,406,767); Yamaoka et al (USPN 5,616,420).

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37

CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher P Bruenjes whose telephone number is 703-305-3440. The examiner can normally be reached on Monday thru Friday from 8:00am-4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Harold Pyon can be reached on 703-308-4251. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9310 for regular communications and 703-872-9311 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0661.

Christopher P Bruenjes
Examiner
Art Unit 1772

CPB
June 13, 2003

HAROLD PYON
SUPERVISORY PATENT EXAMINER
1772

6/13/03